K033633

FEB 18 2004

510(k) SUMMARY

Submitter's Information	VasCon LLC 9344 NW 13 Street Miami, Florida 33172 USA Telephone: 1.305.477.2406 Fax: 1.305.592.6605 Contact: Stephen F. Vadas, Ph.D.
Preparation Date	18 November 2003
Name of Device	Common Name: Guiding Catheter Classification Name: Percutaneous Catheter Trade Name: VasCon Polaris™ Guiding Catheter
Predicate Device	Cordis Guiding Catheters (Vista BRITE TIP®)
Intended Use	The guiding catheter is intended for use for intravascular introduction of interventional / diagnostic devices into the coronary or peripheral vascular systems.
Device Description and Summary of Technological Characteristics	The VasCon Polaris™ Guiding Catheters are single lumen catheters, incorporating a nylon body reinforced with a stainless steel wire braid, a PTFE lubricious inner lumen, and a soft radiopaque tip to reduce potential vessel injury. They are available in 5Fr, 6Fr, 7Fr, and 8Fr, 100 cm in length, and in a variety of shapes. The technological characteristics are equivalent to the predicate device.
Testing Summary	Laboratory testing has been performed on the VasCon Polaris™ Guiding Catheters to assure compliance to the specifications. In addition, laboratory testing has been performed on the materials to assure biocompatibility.
Conclusions	The testing as discussed above demonstrate that, like the predicate devices, the VasCon Polaris™ Guiding Catheters are safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 2004

VasCon LLC
c/o Stephen P. Vadas, Ph.D.
Vice President, Product Assurance & Regulatory Affairs
9344 NW 13th Street
Miami, FL 33172

Re: K033633
Trade Name: VasCon Polaris Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Percutaneous
Regulatory Class: Class II (two)
Product Code: DQY
Dated: November18, 2003
Received: November 19, 2003

Dear Dr. Vadas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Bachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033633

Device Name: VasCon Polaris™ Guiding Catheter

Indications For Use: The guiding catheter is intended for use for intravascular introduction of interventional / diagnostic devices into the coronary or peripheral vascular systems.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna B. Lochner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033633